



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARDS OF PATENT APPEALS AND INTERFERENCES**

In re Application of: Lars Morch Groth

Serial No.: 09/921,429

Group Art Unit: 3728

Filed: August 2, 2001

Examiner: Pickett, John G.

For: A needle magazine

Appeal No.:

BRIEF FOR APPELLANT

6200.200-US Appeal Brief
TABLE OF CONTENTS

	<u>Page</u>
I. Real party in interest	3
II. Related appeals and interferences	4
III. Status of claims	5
IV. Status of amendments	6
V. Summary of claimed subject matter	7
VI. Grounds of rejection to be reviewed on appeal	10
VII. Argument	11
A. Rejection of claims 19-22 under 35 U.S.C. § 103	11
1. Argument for independent claim 19	11
(a) The present invention	11
(b) Grounds of Final Rejection	13
(c) Nguyen et al. and Current fails to establish a prima facie case of obviousness	13
(i) <u>In re Japikse</u> is not relevant to the present case	14
(ii) Nguyen et al. explicitly teaches away from the present invention	15
(iii) Nguyen et al. implicitly teaches away from the present invention	15
(iv) Current fails to teach a compact needle magazine	16
2. Argument for independent claim 21	17
3. Argument for independent claim 22	17
B. Conclusion	19
VIII. Claims appendix	20
IX. Evidence appendix	23
X. Related proceedings appendix	24

I. Real party in interest

The name of the real party in interest is Novo Nordisk A/S, a Danish corporation having offices at Novo Alle, DK-2880 Bagsvaerd, Denmark.

II. Related appeals and interferences

There are no related appeals or interferences.

III. Status of claims

Claims 1-18 are cancelled. Claims 19-22 stand rejected of which claims 19-22 are the subject of this appeal.

IV. Status of amendments

With letter dated December 14, 2004 applicant filed an amended claim 22 and requested the Examiner to enter the amended claim, the amendment correcting some typographical errors applicant had noticed.

The Examiner deemed the amendment to be non-compliant with 37 CFR 1.121 as it failed to list all of the claims. With letter dated January 25, 2005 applicant filed a complete set of claims including the previously presented amended claim 22 and requested the Examiner to enter the amended set of claims. As of January 26, 2005 the request to enter the amendment is pending before the Examiner, however, the Examiner indicated on January 26, 2005 that he would enter the amendment.

V. Summary of claimed subject matter

Independent claim 19 recites “A tool for attaching a pen needle assembly, which comprises a hub (12, fig. 2) and needle cannula (11, fig. 2) mounted to the hub, to an injection device (13, fig. 2) that has a needle mounting surface disposed thereon, the tool comprising:

- a. a cylindrical storage member (1, fig. 2) having elongated cavities (9, fig. 2) complementary in size and shape to the pen needle assembly, the cavities arranged radially in the cylindrical member so as to allow the tool to rotate about an axis of rotation that is concentric with the cavity's longitudinal axis (page 1, line 30 to page 2, line 2);
- b. a rotatable cover (5, fig. 2, page 5, lines 20-22) mounted on the storage member having a cylindrical wall and having an opening (6, fig. 1) that allows access to one cavity at a time;
- c. a removeably sterility barrier (14, fig. 1) sealing the cavities;

wherein: the height of the cylindrical member and cover are sized so as to allow a user to grasp the tool in one hand and to rotate the tool in one hand 360 degrees about the axis of rotation while simultaneously allowing the user to rotate the injection device 360 degrees in an other hand (page 3, lines 10-14), wherein when the tool is grasped in the hand of a user, the majority of rotational force applied to the tool occurs at a distance displaced away from the axis of rotation of the tool, thereby maximizing the rotational force on the pen needle assembly (page 3, lines 16-20).”

Independent claim 21 recites “A method of mounting a pen needle assembly, which comprises a hub (12, fig. 2) and needle cannula (11, fig. 2) mounted to the hub, to an injection device (13, fig. 2) that has a needle mounting surface disposed thereon, the method comprising the steps of: obtaining a tool that comprises:

- a. cylindrical storage member (1, fig. 2) having elongated cavities (9, fig. 2) complementary in size and shape to the pen needle assembly, the cavities arranged radially in the cylindrical member so as to allow the tool to rotate about an axis of rotation that is concentric with the cavity's longitudinal axis (page 1, line 30 to page 2, line 2);

- b. a rotatable cover (5, fig. 2, page 5, lines 20-22) mounted on the storage member having a cylindrical wall and having an opening (6, fig. 1) that allows access to one cavity at a time;
- c. a removeably sterility barrier (14, fig. 1) sealing the cavities;

wherein: the diameter of the cylindrical member and the cover is substantially larger than the height of the cylindrical member and cover (fig. 1), respectively; the height of the cylindrical member and cover are sized so as to allow a user to grasp and rotate the tool in one hand 360 degrees about the axis of rotation while simultaneously allowing the user to rotate the injection device 360 degrees in an other hand (page 3, lines 10-14), wherein when the tool is grasped in the hand of a user, the majority of rotational force applied to the tool occurs at a distance displaced away from the axis of rotation of the tool, thereby maximizing the rotational force on the pen needle assembly (page 3, lines 16-20); removing the sterility barrier;

grasping the tool in one hand and the injection device in another; rotating the tool 360 degrees, rotating the injection device 360 degrees; wherein the grasping of the tool occurs at a distance displaced away from the axis of rotation of the tool so as to maximize the rotational force on the pen needle assembly (page 3, lines 16-20).”

Independent claim 22 recites “A needle storage and mounting apparatus for storing a plurality of pen needles (11, 12, fig. 2) and mounting one of the needles onto an injection device (13, fig. 2), the apparatus comprising: a cylindrical body (1, fig. 2) having radial cavities (9, fig. 2) complementary in shape to the pen needles; a cylindrical cover (5, fig. 2) having one opening (6, fig. 1) for accessing one cavity at a time, the cover being rotatable (5, fig. 2, page 5, lines 20-22) so that the opening can be rotated over a cavity; a *means* for preventing the opening in the cover from being rotated over the same opening more than once (page 4, lines 10-15); a *means* for preventing rotation of the pen needle while the needle is in the cavity; and wherein the apparatus has a height [less] and diameter and wherein the diameter is substantially greater than the height so that a user may grasp the apparatus in one hand, exert a rotational force on the apparatus at a two points equidistant from the pen needle thereby maximizing the rotational force on the pen needle and assisting in screwing the pen needle onto the injection device (page 3, lines 14-20).

Independent claim 22 recites (i) “means for preventing the opening in the cover from being rotated over the same opening more than once” and (ii) “means for preventing rotation of

the pen needle while the needle is in the cavity. These are means plus function recitations as permitted by 35 U.S.C. § 112, paragraph 6. The structures described in the specification as corresponding to these means are respectively (i) a plurality of ratchet teeth provided on the base member interacting with one or more ratchet teeth provided on the cover (29, 30, fig. 4, page 4, lines 13-15) and (ii) force fitting of each needle assembly into each needle compartment (11, 12, 9, fig. 2, page 4, lines 24-26) or longitudinal tracks or ribs provided on the hub and fitting into similar tracks or ribs located on the interior surface of the needle compartment (fig. 2, page 4, lines 26-29).

VI. Grounds of rejection to be reviewed on appeal

Claims 19-22 stand rejected under 35 U.S.C § 103 as being unpatentable over Nguyen et al. (US patent 5,873,462) in view of Current (US patent 4,203,518).

Independent claims 19, 21 and 22 are argued separately, dependent claim 20 stands and falls with claim 19.

VII. Argument

A. Rejection of claims 19-22 under 35 U.S.C. § 103 based upon combination of Nguyen et al. and Current

1. Argument for independent claim 19

(a) The present invention

Claim 19 is directed to a tool for attaching a pen needle assembly to an injection device, the tool comprising a plurality of radially arranged cavities for each holding a pen needle assembly.

Conventional needle magazines typically comprise a base or storage member having a plurality of compartments each containing a needle assembly comprising a hollow infusion needle mounted on a hub portion. The compartments have a longitudinal configuration corresponding to the longitudinal configuration of the typical needle assembly and are arranged in an “upright” position defining the height of the needle magazine. A needle magazine known from Nguyen et al., US patent 5,873,462 comprises a cylindrical base member on top of which a cover with a slot is rotatable mounted such that aligning the slot with the interior of a compartment allows a user to access the compartment and the therein contained needle. Specification page 1, lines 18-28. When the needle assemblies are adapted for threaded connection with an injection device the user will have to rotate the pen relative to the needle magazine, however, as the compartments are arranged on the periphery of the known needle magazine, in practice only the pen can be rotated by the user. As the pen normally is slender in configuration, this only allows the user to apply a limited amount of rotational force between the pen and the needle assembly, just as the entire relative rotation, e.g. 720 degrees, between the needle assembly and the pen would have to be provided by rotating the pen relative to the needle magazine. Specification page 1, line 30 to page 2, line 2.

In accordance with the present invention, applicant has found that a re-arrangement in which the cavities are arranged radially in the cylindrical storage member provides a needle magazine with unexpected advantages such that a needle magazine of the claimed configuration

allows the needle magazine to be used as a tool for securing needle assemblies to injection devices, and not merely as a magazine for storing needle assemblies.

More specifically, the radial arrangement of the cavities provides several advantages allowing the needle magazine of the present invention to be used as an effective tool for attachment (as well as detachment) of a needle assembly to an injection device.

First, by arranging the cavities radially, rotation of the needle magazine corresponding to an axis concentric with a given cavity's longitudinal axis will provide a rotational movement between the corresponding needle assembly and an injection device placed in engagement therewith, this allowing a threaded connection between the needle assembly and the injection device to be established. Indeed, the injection device may also be rotated relative to the needle magazine, e.g. the present invention would allow needle assemblies to be mounted on injection devices by rotating the magazine 360 degrees and rotating the injection device 360 degrees in an opposite direction. This said, the present invention would of course also allow a 720 degree rotation to be split differently.

Second, by providing a needle magazine which can be used as a rotational tool, a greater leverage and thus torque can be provided between the needle assembly and the injection device. Although substantially the same torque has to be applied to both the needle magazine and the injection device when a needle assembly is threaded onto the injection device (i.e. the principle of balanced forces), it is easier for a user to arrest the injection device (which typically is pen-shaped), and then provide a high torque between the needle assembly and the injection device by rotating the needle magazine. This especially is the case when the needle assembly is tightened and un-tightened. Also, a user may use the stronger hand to arrest the pen and then use the weaker hand to rotate the needle magazine, the configuration of the needle magazine "compensating" for the weakness.

Third, by arranging the cavities radially a "flat" needle magazine is provided having a low height and a relative large width, the low height making the needle magazine easy to grip between the fingers, the large width providing a high leverage and thus torque when rotated. For example, when the needle magazine is grasped at two opposite points along its circumference and the needle assembly being fastened or unfastened is centered between these two points, leverage is maximized, this allowing the needle magazine to be used as a wrench.

(b) Grounds of Final Rejection

In the Final Rejection claims 19-22 were rejected under 35 U.S.C § 103 as being unpatentable over Nguyen et al. (US patent 5,873,462) in view of Current (US patent 4,203,518).

Thus, the Examiner has essentially argued that it would have been obvious for the skilled person to modify the needle magazine of Nguyen et al. by adopting the radial arrangement of the needles in the needle magazine of Current, the motivation being height reduction, hereby allegedly establishing a *prima facie* case of obviousness.

(c) Nguyen et al. and Current fails to establish a *prima facie* case of obviousness

As recognized by the Examiner, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See Office Action dated January 30, 2004, Section 11 in which the Examiner cited *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 D.2d 347, 21 USPQ2d 1596 (Fed. Cir. 1992).

The Examiner has failed to identify a teaching, suggestion, or motivation in Nguyen et al., or in any other document on file, to modify the disclosed needle magazine. The Examiner has thus in this case consequently and explicitly relied solely on the argument that the motivation can be found in the knowledge that was generally available to one of ordinary skill in the art at the time the invention was made, i.e. that it was a well established principal of design of portable objects to limit overall size. See Office Action dated January 30, 2004, Section 11. In support of the rejection the Examiner has cited *In re Japikse*, 86 USPQ 70 in which it was held that a given modification was unpatentable because the modification did not change the operation of the device. See Final Office Action dated July 29, 2004, Section 5.

However, by doing so the Examiner has ignored the fact that the intended modification, i.e. arranging the needle cavities radially, has modified the operation of the Nguyen needle magazine. Further, the alleged obvious modification is also in contrast to what Nguyen et al. explicitly holds as being their invention. Further again, Current does not provide a teaching that a radial arrangement of the needles provides a more compact device with a reduced overall size.

(i) In re Japikse is not relevant to the present case

In In re Japikse it was held that a given modification was unpatentable because the modification did not change the operation of the device. More specifically, Claim 3 of In re Japikse was concerned with a hydraulic power press in which transfer tables with covers were moved to and from a supporting means in alignment with a platen. The covers had depending means adapted to pass through aligned openings in the supporting means. Such a press was known from Cannon (US patent 2,317,440). The Cannon press used the depending means in order to control movement of the cover in its outermost positions by deceleration. Cannon further states that “[t]he press is equipped with various electric switches which control the operation of the moving parts of the press and with suitable dogs for actuation various electric switches. As is well known to those skilled in the design, construction and operation of presses, such dogs and the switches with which they coact may be mounted optionally in various positions...” See Cannon page 5, left column, lines 49-57. In the disclosed embodiment “[the] magnet 218 is energized upon completion of the “in” movement of carrier B by reason of switch B32 being actuated by dog B2. Upon magnet 218 thus becoming energized, switch 218c in the circuit of magnet 221 is caused to close to initiate closing of the press”. See Cannon page 10, right column, lines 39-45.

In other words, Cannon teaches that a contact should be arranged between the moving carrier and a non-moving portion of the press in order to start operation of the press.

In In re Japikse the Board found that claim 3 read on Cannon except from the limitation reading “means disposed in alignment with said opening for contact by said depending means to start the pressing operation of said hydraulic press” and held that there was no invention in shifting the starting switch disclosed by Cannon to a different position since the operation of the device would not thereby be modified.

Although not explicitly relied upon by the Board it is to be noted that the contact was also arranged corresponding to the explicit teaching of Cannon on how to arrange the contact in order to control operation of the press.

In the present case the Examiner has cited In re Japikse in support of the argument that the modifications of the present invention are unpatentable because the modifications over Nguyen et al. did not change the mode of operation of the device

Having regard to the above analysis, applicant respectfully disagrees with the relevance of In re Japikse for the following reasons: (i) As will be set out in detail below the present invention provides a needle magazine which in a substantial way modifies the operation of the needle magazine of Nguyen et al, this in contrast to the above-presented facts of In re Japikse (ii) Nguyen et al. does not teach, neither explicitly nor implicitly to rearrange the needle cavities in a different way from the disclosed embodiment, this in contrast to the explicit teaching on how to modify the press found in Cannon.

(ii) Nguyen et al. explicitly teaches away from the present invention

35 U.S.C § 112, second paragraph, states that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention”. In other words, what is defined in the claims of Nguyen et al. must represent the strongest possible way of setting out what Nguyen et al. considered as their invention.

Correspondingly, Nguyen et al. specifically discloses that the needle cavities have to be arranged in the upper surface of the container. More specifically, claim 1 defines an apparatus for storing a plurality of needle assemblies, comprising among others “a container having an upper surface including a plurality of cavities (emphasis added) for receiving each of said plurality of needle assemblies therein”.

In other words, the arrangement of the needle cavities in the upper surface as depicted in fig. 2 cannot be considered merely an embodiment of the invention but must be regarded as representing the invention *per se* and any suggestion to modify this feature must be considered against the clear teaching of Nguyen et al.

(iii) Nguyen et al. implicitly teaches away from the present invention

For a moment disregarding the strong and explicit teaching of Nguyen et al, this document also implicitly teaches away from modifying the known needle magazine in accordance with the present invention.

Nguyen et al. discloses a needle magazine basically in the form of a cylinder with a plurality of openings formed in an upper surface thereof. See fig. 2. Although Nguyen et al. is silent as to the way of operating the disclosed needle magazine, this design lends itself to be used either with the needle magazine arranged on a supporting surface with the cavities facing upwardly, or by being placed and held in the palm of the user with the cavities facing away from the palm. It is submitted that any other way of use of the Nguyen et al. needle magazine would be awkward and that the above described ways of use is the ones intended by Nguyen et al.

Now, if the cavities of the Nguyen et al. needle magazine were rearranged radially in accordance with the present invention, would it then be possible to use the needle magazine in what must be assumed to be the intended ways? Considering the proposed new configuration of the cavities, it readily appears that this would no longer be possible. For example, when a needle magazine with radially arranged needle cavities is supported on a surface it would no longer be possible to connect an injection device unless the latter was held in a most awkward way. Correspondingly, it would also be awkward to connect an injection device when a needle magazine with radially arranged needle cavities is supported in the palm of the user.

As follows from the above, when the cavities in a needle magazine are arranged radially, the user will have to use the needle magazine in a different way, e.g. by gripping the upper and lower surfaces of the needle magazine between the fingers. Indeed, it is partly this different way of use that provides the surprising advantages associated with the present invention.

(iv) Current fails to teach a compact needle magazine

The Examiner has argued that Current provides a teaching on how to reduce the overall height of a needle container. Applicant respectfully disagrees with this position.

More specifically, Current has as the stated objects to provide a package for sewing machine needles in which (i) the needles can be segregated in individual compartments, in which (ii) information concerning the proper choice of needles for a particular thread or fabric is selectively displayed as a consequence of choosing a particular needle compartment, and in

which (iii) individual storage compartments can be selectively accessed. See column 1, lines 29-40.

In accordance with these objects Current provides a needle package with a plurality of walls radiating outwardly from a hub and defining a plurality of needle storage compartments. See fig. 1.

There is no teaching, neither explicitly nor implicitly, to be found in Current that it was an object to provide a needle package or container with a reduced height compared to known needle packages, or that the disclosed solution to the stated problems provides a needle package with a reduced height.

Thus, applicant submits that it is only with impermissible hindsight and knowledge of the present invention that it can be argued that Current teaches the skilled person how to provide a needle magazine with reduced height.

Further, even if it may be argued that Current provides a needle magazine for sewing needles with reduced height, it is not evident from Current that this would also be the case for needle assemblies for injection devices as disclosed in Nguyen et al.

2. Argument for independent claim 21

Claim 21 recites a method of mounting a pen needle assembly to an injection device using a needle magazine as recited in claim 19 as a tool, the method comprising the steps of rotating the magazine 360 degrees and rotating the injection device 360 degrees, wherein the tool is grasped at a distance from the axis of rotation of the tool so as to maximize the rotational force on the pen needle assembly. Specification page 3, lines 10-20.

As appears, method claim 21 defines a very specific method of using the present invention by rotating both the magazine and the injection device 360 degrees in order to achieve a combined rotation between the two elements of 720 degrees. No specific arguments have been presented by the Examiner with regard to this method step.

In respect of the needle magazine *per se*, the same arguments as presented in above in support of claim 19 apply to claim 21.

3. Argument for independent claim 22

Claim 22 recites a needle storage and mounting apparatus for storing a plurality of pen needles and mounting one of the needles onto an injection device. Although worded differently claim 22 incorporates the same inventive features as set out in claim 19, namely a cylindrical body having radial cavities for the pen needles, and wherein the apparatus is dimensioned so as to allow a user to grasp the apparatus with one hand and use it as a tool to rotate a pen needle and thereby assisting in screwing the pen needle onto an injection device.

Thus, the same arguments as presented above in support of claim 19 apply to claim 22.

B. Conclusion

Applicant submits that the following has been demonstrated:

The Examiner has failed to establish a *prima facie* case of obviousness based on Nguyen et al. in view of Current.

More specifically,

- In re Japikse cannot be considered relevant to the present case,
- Nguyen et al. does not provide a teaching or motivation to modify the disclosed needle magazine,
- the proposed modification of Nguyen et al. substantially changes the operation of the disclosed needle magazine,
- Nguyen et al. explicitly teaches away from the present invention, and
- Nguyen et al. implicitly teaches away from the present invention.

Further,

- Current fails to teach a compact needle magazine.

In contrast, applicant has demonstrated that the present invention provides unexpected advantages, thereby establishing secondary indicia of non-obviousness.

For the reasons set out above, applicant respectfully request that the rejection of claims 19-22 be set aside.

Respectfully submitted,



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VIII. Claims appendix

Claims on appeal

19. A tool for attaching a pen needle assembly, which comprises a hub and needle cannula mounted to the hub, to an injection device that has a needle mounting surface disposed thereon, the tool comprising:

- a. a cylindrical storage member having elongated cavities complementary in size and shape to the pen needle assembly, the cavities arranged radially in the cylindrical member so as to allow the tool to rotate about an axis of rotation that is concentric with the cavity's longitudinal axis;
- b. a rotatable cover mounted on the storage member having a cylindrical wall and having an opening that allows access to one cavity at a time;
- c. a removeably sterility barrier sealing the cavities;

wherein: the height of the cylindrical member and cover are sized so as to allow a user to grasp the tool in one hand and to rotate the tool in one hand 360 degrees about the axis of rotation while simultaneously allowing the user to rotate the injection device 360 degrees in an other hand, wherein when the tool is grasped in the hand of a user, the majority of rotational force applied to the tool occurs at a distance displaced away from the axis of rotation of the tool, thereby maximizing the rotational force on the pen needle assembly;

20. The tool of claim 19, further comprising a means for preventing rotation of the cover over the same opening more than once.

21. A method of mounting a pen needle assembly, which comprises a hub and needle cannula mounted to the hub, to an injection device that has a needle mounting surface disposed thereon, the method comprising the steps of:

- obtaining a tool that comprises
 - a. cylindrical storage member having elongated cavities complementary in size and shape to the pen needle assembly, the cavities arranged radially in the cylindrical

member so as to allow the tool to rotate about an axis of rotation that is concentric with the cavity's longitudinal axis;

- b. a rotatable cover mounted on the storage member having a cylindrical wall and having an opening that allows access to one cavity at a time;
- c. a removeably sterility barrier sealing the cavities;

wherein: the diameter of the cylindrical member and the cover is substantially larger than the height of the cylindrical member and cover, respectively; the height of the cylindrical member and cover are sized so as to allow a user to grasp and rotate the tool in one hand 360 degrees about the axis of rotation while simultaneously allowing the user to rotate the injection device 360 degrees in an other hand, wherein when the tool is grasped in the hand of a user, the majority of rotational force applied to the tool occurs at a distance displaced away from the axis of rotation of the tool, thereby maximizing the rotational force on the pen needle assembly;

- removing the sterility barrier;
- grasping the tool in one hand and the injection device in another;
- rotating the tool 360 degrees;
- rotating the injection device 360 degrees;

wherein the grasping of the tool occurs at a distance displaced away from the axis of rotation of the tool so as to maximize the rotational force on the pen needle assembly.

22. (amended) A needle storage and mounting apparatus for storing a plurality of pen needles and mounting one of the needles onto an injection device, the apparatus comprising:

- a cylindrical body having radial cavities complementary in shape to the pen needles;
- a cylindrical cover having one opening for accessing one cavity at a time, the cover being rotatable so that the opening can be rotated over a cavity;
- a means for preventing the opening in the cover from being rotated over the same opening more than once;
- a means for preventing rotation of the pen needle while the needle is in the cavity;
- and wherein the apparatus has a height and diameter and wherein the diameter is substantially greater than the height so that a user may grasp the apparatus in one hand, exert a rotational force on the apparatus at a two points equidistant from the pen needle thereby

maximizing the rotational force on the pen needle and assisting in screwing the pen needle onto the injection device.

IX. Evidence appendix

No evidence has been entered or relied upon in the appeal.

X. Related proceedings appendix

There are no related appeals or interferences.